

Food and Drug Administration, HHS

§ 529.778

(b) *Approvals*. See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(c) *Conditions of use*—(1) *Amount*. Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use*. For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.

(3) Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 7072, Feb. 15, 2002, as amended at 79 FR 10973, Feb. 27, 2014]

§ 529.56 Amikacin.

(a) *Specifications*. Each milliliter (mL) of solution contains 250 milligrams of amikacin as amikacin sulfate.

(b) *Sponsors*. See Nos. 000859 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 2 grams (8 mL) diluted with 200 mL of sterile physiological saline by intrauterine infusion daily for 3 consecutive days.

(2) *Indications for use*. For treating genital tract infections (endometritis, metritis, and pyometra) in mares caused by susceptible organisms including *Escherichia coli*, *Pseudomonas* spp., and *Klebsiella* spp.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 17339, Mar. 29, 2011, as amended at 78 FR 17597, Mar. 22, 2013; 79 FR 10973, Feb. 27, 2014]

§ 529.400 Chlorhexidine tablets and suspension.

(a) *Specification*. Each tablet and each 28-milliliter syringe of suspension contain 1 gram of chlorhexidine dihydrochloride.¹

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Place 1 or 2 tablets deep in each uterine horn; or infuse a solution of 1 tablet dissolved in an appropriate amount of clean boiled water; or infuse one syringe of suspension into the uterus.

(2) *Indications for use*. For prevention or treatment of metritis and vaginitis in cows and mares when caused by pathogens sensitive to chlorhexidine dihydrochloride.

(3) *Limitations*. Prior to administration, remove any unattached placental membranes, any excess uterine fluid or debris, and carefully clean external genitalia. Use a clean, sterile inseminating pipette for administering solutions and suspensions. Treatment may be repeated in 48 to 72 hours.

[43 FR 10705, Feb. 23, 1979, as amended at 79 FR 10973, Feb. 27, 2014]

EDITORIAL NOTE: At 79 FR 10973, Feb. 27, 2014, § 529.400 was amended to revise the section heading, however, the section heading was not provided, therefore, the amendment could not be incorporated due to inaccurate amendatory instruction.

§ 529.536 Detomidine.

(a) *Specifications*. Each milliliter of gel contains 7.6 milligrams (mg) of detomidine hydrochloride.

(b) *Sponsor*. See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 0.018 mg per pound (mg/lb) (0.040 mg/kilogram (kg) sublingually.

(2) *Indications for use*. For sedation and restraint.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use in horses intended for human consumption.

[75 FR 21163, Apr. 23, 2010, as amended at 76 FR 16533, Mar. 24, 2011]

§ 529.778 Doxycycline.

(a) *Specifications*. Doxycycline hyclate solution contains 8.5 percent doxycycline activity. A syringe of N-methyl-2-pyrrolidone and poly (DL-lactide) mixed with a syringe of doxycycline produces 0.5 milliliter of solution.